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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/665,117	09/22/2003	Kieko Morita	030096A	5419

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EXAMINER	
JONES, DAMERON LEVEST	
ART UNIT	PAPER NUMBER
1616	

DATE MAILED: 07/28/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/665,117	MORITA, KIEKO	
	Examiner	Art Unit	
	D. L. Jones	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 May 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *23 and 26-29* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *23 and 26-29* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

ACKNOWLEDGMENTS

1. The Examiner acknowledges receipt of the amendment filed 5/27/04 wherein the claim status is as follows: claims 1-22, 24, and 25 were canceled; claims 23, 26, and 27 were amended; and claims 28 and 29 were added.

Note: Claims 23 and 26-29 are pending.

RESPONSE TO APPLICANT'S ELECTION

2. Applicant's election with traverse of Group VIII (claims 26 and 27) filed 5/27/04 is acknowledged. The traversal is on the ground(s) that Groups VI has been amended to feature similar parameters as set forth in Group VIII. This is found non-persuasive because Applicant has amended the claims to contain overlapping subject matter. Thus, claims 23 and 26-29 will be examined and the restriction requirement is still deemed proper and is therefore made FINAL.

Note: It should be noted that Applicant elected to prosecute the claims wherein the species is the biological marker, cortisol. The search was not expanded beyond cortisol and Alzheimer's disease because prior art was found which could be used to reject the claims. In Applicant's response filed 5/27/04, it is stated that claims 28 and 29 correspond to claims 23 and 26, but are specifically directed to Alzheimer's disease.

112 FIRST PARAGRAPH REJECTION

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the

art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 23, 26, and 27 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the biological marker cortisol and mental and neurological disorders selected from the group consisting of Alzheimer's disease, schizophrenia, dementia, epilepsy, seizures, bipolar disorder, manic depression, autism multiple sclerosis, Parkinson's disease, Huntington's disease, and systemic lupus eythematosus, does not reasonably provide enablement for all biological markers and mental and neurological disorders. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

There are several guidelines when determining if the specification of an application allows the skilled artisan to practice the invention without undue experimentation. The factors to be considered in determining what constitutes undue experimentation were affirmed by the court in *In re Wands* (8 USPQ2d 1400 (CAFC 1986)). These factors are (1) nature of the invention; (2) state of the prior art; (3) level of one of ordinary skill in the art; (4) level of predictability in the art; (5) amount of direction and guidance provided by the inventor; (6) existence of working examples; (7) breadth of claims; and (8) quantity of experimentation needed to make or use the invention based on the content of the disclosure.

(1) Nature of the invention

The claims are directed to methods of treating and detecting mental or neurological disorders wherein a biological marker is analyzed.

(2) State of the prior art

The references do not all possible biological markers and mental and neurological disorder for which cortisol levels are analyzed to detect or treat a disorder.

(3) Level of one of ordinary skill in the art

The level of one of ordinary skill in the art is high. Independent claims 23, 26, 28, and 29 encompasses a vast number of possible biological markers and mental and neurological disorders. Applicant's specification does not enable the public to make or use such a vast number of possible biological markers in combination with their respective mental and neurological disorder.

(4) Level of predictability in the art

The art pertaining to biological markers and mental and neurological disorders is highly unpredictable. Determining the various types or class of biological markers in combination with the mental or neurological disorder requires various experimental procedures and without guidance that is applicable to all biological markers and mental and neurological disorders, there would be little predictability in performing the claimed invention. Hence, there is little predictability in performing the claimed invention, absent some guidance.

(5) Amount of direction and guidance provided by the inventor

Independent claims 23 and 26 encompass a vast number of biological markers and mental and neurological disorders. Applicant's limited guidance does not enable the public to prepare such a numerous amount of markers or determine the mental or neurological disorder of interest. There is no directional guidance for the biological

marker-mental/neurological disorder combinations. Hence, there is no enablement for all possible permutations and combinations of the biological markers and mental and neurological disorders.

(6) Existence of working examples

Independent claims 23 and 26 encompass a vast number of biological markers and mental or neurological disorder combinations. Applicant's limited working examples do not enable the public to prepare such a numerous amount of biological marker-mental/neurological disorder combination. While Applicant's claims encompass a plethora of possible biological markers and mental and neurological disorders, the specification provides for the biological marker cortisol and mental and neurological disorders selected from the group consisting of Alzheimer's disease, schizophrenia, dementia, epilepsy, seizures, bipolar disorder, manic depression, autism multiple sclerosis, Parkinson's disease, Huntington's disease, and systemic lupus eythematosus.

(7) Breadth of claims

The claims are extremely broad due to the vast number of possible biological markers and mental and neurological disorders known to exist.

(8) Quantity of experimentation needed to make or use the invention based on the content of the disclosure

The specification does not enable any person skilled in the art to which it pertains to make or use the invention commensurate in scope with the claims. In particular, the specification fails to enable the skilled artisan to practice the invention without undue

experimentation. Furthermore, based on the unpredictable nature of the invention, the state of the prior art, and the extreme breadth of the claims, one skilled in the art could not perform the claimed invention without undue experimentation.

112 SECOND PARAGRAPH REJECTION

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 23, 26, and 27 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 23, 26, and 27: The claims as written are ambiguous because one cannot readily ascertain what is being claimed. Specifically, the claims as written read on various biological markers and mental and neurological disorders combinations. However, one of ordinary skill in the art would not be able to ascertain what specific biological marker and mental or neurological disorder combination is encompassed in the claim as written. Applicant is respectfully requested to clarify the claim in order that one may determine what is being claimed.

Claims 26 and 27: The claims as written are ambiguous because independent claim 26 reads 'A method of a mental or neurological disorder...CSF'. It is unclear if Applicant is referring to a method of *detecting* or *treating* a mental or neurological disorder. Please clarify in order that one may readily ascertain what is being claimed.

103 REJECTION

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. Claims 23 and 26-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schatzberg et al (US Patent No. 6,369,046).

Schatzberg et al disclose methods of treating dementia (see entire document, especially, abstract). In the background of the invention, Schatzberg et al disclose that dementia has been associated with increased levels of cortisol (column 1, lines 33-34). The dementia may be associated with Alzheimer's disease and cortisol contributes to the rate of cognitive decline in patents with dementia (column 2, lines 50-55; column 3, lines 19-26). In columns 5-6, bridging paragraph, it is disclosed how to assess and diagnosis dementia, in particular, Alzheimer's disease, by analyzing the cerebral function (see also, column 11, lines 4-33); columns 11-12, bridging paragraph. In addition, in diagnosing and assessing dementia of Alzheimer's type is disclose in column 8 (lines 15-59). Dementia of the Alzheimer's type may be determined by computed tomography, magnetic resonance imaging, dynamic susceptibility contrast MRI, positron emission tomography, or single photon emission computed tomography (column 9, lines 39-53). Also, Schatzberg et al disclose that determining blood cortisol levels allow for monitoring of blood cortisol and determining baseline cortisol levels

which can be useful in the diagnosis, treatment, and prognosis of a patient (column 13, lines 10-31). Furthermore, Schatzberg et al disclose that when lower dosages of a drug is administered to a secluded site in the subject (i.e., cerebral spinal fluid), treatment of dementia is also possible. Hence, based on the teachings of Schatzberg et al, it would have been obvious to one of ordinary skill in the art at the time the invention was made to generate a method of treating and detecting Alzheimer's disease by monitoring cortisol levels since (1) the reference discloses that methods of treating/detecting dementia forces on analyzing cortisol levels. (2) The cited prior art discloses that dementia may be associated with Alzheimer's disease. Hence, both the cited prior art and the instant invention are directed to treating and detecting Alzheimer's disease by analyzing cortisol levels.

COMMENTS/NOTES

9. Applicant is respectfully requested to update the status of the applications in the continuing data in the first paragraph of the specification.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. L. Jones whose telephone number is (571) 272-0617. The examiner can normally be reached on Mon.-Fri., 6:45 a.m. - 3:15 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on (571) 272-0887. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

D. L. Jones
Primary Examiner
Art Unit 1616

July 26, 2004